In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-1960V

ERIC and KIMBERLY MONTE, *as natural parents and legal guardians of* D.M., *a minor*, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: January 5, 2024

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioners.

Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On October 4, 2021, Eric and Kimberly Monte filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Program").[2] Petition (ECF No. 1) at 1. Petitioners allege that their son, D.M., developed autoimmune encephalitis, encephalopathy, and/or some unspecified autoimmune-mediated neurologic disorder after receipt of an influenza ("flu") vaccine administered on October 8, 2018. *Id.*

Respondent has moved to dismiss the claim, arguing both that the alleged injuries are not established by the record, and that the flu vaccine could not have caused them in any case, and the matter is now fully briefed for resolution by ruling on the record. *See* Respondent's Brief, dated July 10, 2023 (ECF No. 27) ("Br."); Petitioner's Opposition, dated August 17, 2023 (ECF No. 28) ("Opp.");

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

Respondent's Reply, dated August 31, 2023 (ECF No. 29). After review of the record and the parties' filings, and for the reasons set forth below, I grant Respondent's motion.

I. Factual Background

D.M. was thirteen when he received the flu vaccine on October 8, 2018, at Family First Pediatrics ("FFP"), his primary care provider, in Spring, TX. Ex. 1 at 9. The exam from this visit resulted in no concerning findings, and the record contains no evidence of any immediate reaction to the vaccination. *Id.* at 10; *see also* Declaration of Eric Monte, dated August 4, 2021, filed as Ex. 2 (ECF No. 6-2) ("Monte Decl.") at 2.

Football Injury and Subsequent Neurologic Symptoms

Three days later, on October 11, 2018, D.M. was taken to the emergency department ("ED") of Memorial Hermann Tomball Hospital ("MHTH") in Tomball, TX. Ex. 1 at 37–40. As this record reveals, it was reported at this time that D.M. had experienced a headache after being punched in the chin during a football game the night before (October 10th). *Id.* at 40. Although Mr. Monte has alleged that coaches and teammates at the game did not perceive anything that would have been consistent with D.M. experiencing a head injury, treaters were informed that D.M. had looked "dazed and was breathing heavily" when encountered at the end of the game, and later that same night "started wandering around the house dazed and confused." Monte Decl. at 2.

ED treating physicians performed a CT scan that produced normal results, with no evidence of underlying abnormalities or developmental concerns. Ex. 1 at 39. They diagnosed D.M. with a concussion, discharging him before eight p.m. that evening. *Id.* at 38. Later that same day, D.M. went to FFP and was examined by Dr. Tad Shirley. *Id.* at 8–9. The record from this visit provides more details about the football injury, characterizing it as the product of a "hard hit," and noting that even though "no one noticed anything during the game," afterward D.M. seemed "out of it" and displayed some short-term memory loss, along with other uncharacteristic behaviors. *Id*. at 8. Indeed, Dr. Shirley was told (presumably by Mrs. Monte, based on the context of the record) that D.M. that very morning could not remember where the bathroom in his home was, and seemed confused about getting dressed when handed a shirt. *Id.* D.M.'s injury was again characterized as concussion, and he was advised to see a specialist and otherwise avoid sports for a period of time. *Id.* at 9.

A week later, D.M. went to the Houston Institute of Neurology for Kids ("THINK") on October 16, 2018, for an appointment with neurologist Asra Akbar, M.D. Ex. 1 at 41–45. Mrs. Monte informed Dr. Akbar that D.M. had "sustained several concussions" at the October 10th football game, and subsequently displayed confusion and memory loss, with these symptoms continuing. *Id*. at 41. This record also references a visit to a different treater in the intervening period, and that an MRI of D.M.'s brain had been performed but revealed normal results. *Id.*[3] D.M.'s exam at this time was otherwise

[3] I have not been able to locate the underlying MRI record itself in the filed records, although it may well exist. Reference to it is made elsewhere in the filed records. *See, e.g.*, Ex. 1 at 120.

normal, and he was assessed with "[e]ncephalopathy, unspecified," and directed to undergo an electroencephalogram ("EEG") to check for seizure activity as well as other testing and follow-up. *Id.* at 42. The EEG testing ultimately resulted in normal findings, and did not identify evidence of seizure activity either. Ex. 6 at 5–7.

On November 1, 2018, D.M. obtained a neuropsychological evaluation from Kenneth Podell, Ph.D. Ex. 10 at 3–6. Dr. Podell observed that D.M. was experiencing an atypical gait and severe cognitive impairment. *Id.* at 3. In addition, he displayed a flat affect, was unable to interact, and could not open his mouth to answer questions. *Id*. at 4. Dr. Podell deemed D.M.'s presentation to be highly atypical, and he revealed severe dysfunction on neuropsychological measures inconsistent with what would be expected for someone with only a mildly traumatic brain injury, like a concussion. *Id*. at 5. Dr. Podell opined, however, that D.M.'s presentation (coupled with comments Mrs. Monte had made during the evaluation about stress in their home) suggested a significant "somatization"[4] component (meaning the expression of psychological or emotional factors as physical (somatic) symptoms). *Id.* Dr. Podell nevertheless recommended that (in addition to follow-up psychological and psychiatric treatment) "a more extensive neurological assessment to rule out an acute infectious or inflammatory process may be prudent." *Id.* Mrs. Monte did subsequently inform Dr. Shirley via phone call about this evaluation, and that a psychologist visit had been recommended. Ex. 1 at 8.

Hospitalization and Suspicion of Vaccine Causation

D.M. subsequently returned to MHTH on November 12, 2018, and was treated by Christine Koerner, M.D. Ex. 7 at 102–08. Petitioners now reported that over the prior twenty-four hours, D.M. had displayed increasing weakness and worsened cognitive issues, along with movement issues and an inability to speak above a whisper. *Id*. His physical exam was normal, however, and a review of prior blood testing and CT/MRI results had similarly discerned nothing abnormal. *Id.* Dr. Koerner nevertheless decided to admit him for observation and further neurological work-up. *Id.*

D.M. was thereafter admitted to Memorial Hermann Children's Hospital ("MHCH"), remaining hospitalized until November 21, 2018. Ex. 1 at 51–119. During this timeframe, he underwent psychiatric evaluations, and although it was again thought wise for D.M. to be tested for the possibility of some infectious/autoimmune illness, treaters nevertheless proposed he more likely was suffering from conversion disorder. *Id*. at 62–67. Other treaters similarly concluded that D.M. was most properly diagnosed with a somatization-associated functional neurologic disorder and/or concussion. *Id*. at 54–56, 60.

At the same time, however, D.M. had a rheumatologic consultation with Ankur Kamdar, M.D. Ex. 1 at 84–85. Dr. Kamdar observed that in the overall course of his hospitalization, D.M. had received intravenous steroid therapy that appeared to have arrested or improved many of his symptoms. *Id*. at

[4] "Somatization" is defined as "the conversion of mental experiences or states into bodily symptoms." *Somatization*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=46196&searchterm=somatization (last visited on Jan. 5, 2024).

84. Dr. Kamdar speculated that D.M. had encephalopathy of unknown origin, which was now improved, and took special note of the unusual nature of the improvement this treatment had produced. *Id.* at 85. Dr. Kamdar also stated that "[Mr. Monte] was concerned about the flu vaccination prior to [D.M.'s] development of symptoms," but added his own view that "this was not caused by the flu vaccination." *Id.*

After discharge, D.M. returned to FFP for a visit with Dr. Shirley at the end of November 2018. Ex. 1 at 7–8. The history section from this visit includes a statement provided to Dr. Shirley by Mrs. Monte reporting that during D.M.'s hospitalization, "one doctor said they thought [his condition] could be vaccine assoc encephalopathy or auto immune." *Id.* at 7. The record also sets forth Mrs. Monte's intent to proceed with a VAERS[5] report—although Dr. Shirley noted that he could not find documentation in the medical records he had seen "of anyone saying [D.M.'s condition] could be vaccine related from flu vaccine." *Id.* Dr. Shirley's diagnosis was encephalitis, and he directed D.M. to return to school fulltime with no physical activities for three months. *Id.*

Another pediatric neurologist, Dr. Ian Butler, evaluated D.M. in December 2018. *See* Ex. 1 at 120–21. He reviewed D.M.'s overall treatment course to that point, noting his initial, post-football game presentation and subsequent hospitalization. *Id.* at 120. He also reported that "significant improvement" in D.M.'s condition had been observed after a five-day steroid course administered during the November hospitalization. *Id.* But Dr. Butler (consistent with prior contemporaneous treaters) did not conclude from the overall record (including physical exams and various testing and imaging results) that D.M. had likely experienced any autoimmune-caused encephalopathic injury. Rather, he opined that D.M. had experienced "a postconcussive episode with a relative amnesia for the event," adding that he recommended certain calcium channel testing to evaluate the presence of "significant neurological problems following relatively minor head trauma." *Id.* at 121.

Subsequent Treatment

Since the fall of 2018, Petitioners have continued to seek treatment for D.M.'s condition—but the record does not reveal treater acceptance of a vaccine association, let alone agreement that his symptoms are the results of some autoimmune or infectious process.

For example, D.M. was hospitalized from late February to mid-March 2019 in connection with the same kinds of altered mental status and associated symptoms he had displayed before. Ex. 7 at 57–

[5] The Vaccine Adverse Event Reporting System ("VAERS") is a national warning system designed to detect safety problems in U.S. licensed vaccines. *See About VAERS*, VAERS, https://vaers.hhs.gov/about.html (last visited Nov. 28, 2023). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals. But it has been observed in the Program that VAERS data is not particularly probative of causation unless supplemented with other reliable evidence—since a VAERS report only establishes a temporal, post-vaccination occurrence, and thus shines no light on causation itself. *See also Vig v. Sec'y of Health & Human Servs.*, No. 01-198V, 2013 WL 6596683, at *17 (Fed. Cl. Spec. Mstr. Nov. 14, 2013) ("VAERS is a stocked pond, containing only reports of adverse events after vaccinations but no data about the number of vaccines administered or the occurrence of the same adverse event in individuals who have not been vaccinations").

62, Ex. 11 at 66–70. But comprehensive lab testing—including a metabolic panel, complete blood count, urine toxicology screen, and urinalysis—all produced normal or negative results. Ex. 11 at 89–91. While hospitalized, treaters took note of D.M.'s history—and although they considered diagnoses of encephalitis due to infection or autoimmune infection, they deemed psychiatric disorder with catatonic states and flat affect versus conversion disorder "[h]ighest on the differential," especially in light of the extensive testing D.M. had already experienced. *Id*. at 115.

Neurology consults with D.M. in February 2019 (during his hospitalization) reached the same general conclusions. *See, e.g.*, Ex. 11 at 30–33. Based on exam, one treater (Dr. Stuart Fraser) expressed doubt that D.M.'s symptoms had a neurological etiology, but were instead more consistent with a conversion disorder. *Id*. at 33. Dr. Fraser also opined that D.M.'s response to steroids during his prior hospitalization "occurred within a few hours of the initial dose, which is too rapid to be attributable to the steroids themselves, as the cellular effect of steroids do not happen immediately with administration of the medication." *Id*. (Although Dr. Fraser was at this time only a resident, his opinions and treatment recommendations were endorsed by another neurologist, Dr. Michael Watkins). *Id.* Evaluation by a pediatric hospitalist in early March produced consistent diagnostic and treatment views. *See, e.g.*, Ex. 11 at 933–36 (noting that an infectious or autoimmune neurologic disease etiology for D.M.'s symptoms was not corroborated by the extensive work-up he had received, that a conversion disorder diagnosis seemed appropriate, and that additional steroidal treatment was not called for).

There is some evidence from the end of D.M.'s 2019 hospitalization (in March 2019 specifically) that D.M. responded well to use of a sedative, Ativan. Ex. 11 at 978, 981. In particular, he was observed to sit up appropriately and speak in full sentences not long after its administration. *Id.* at 978. However, he had not responded to this medication in the same manner when it had been first administered to him on a trial basis, leading treaters to conclude that a conversion disorder diagnosis remained likely. *Id.* at 964–65 ("[m]ost suspicious for conversion disorder still given response to Ativan"), 978 (noting D.M.'s "marked change in his mental status" after receipt of Ativan, but contrasting it to earlier lack of response, and concluding that partial responsiveness only supported a catatonia diagnosis—whereas the same evidence meant a conversion disorder diagnosis "may still be likely"). Other treaters at this time expressed the opinion that D.M.'s apparent prompt response to steroid treatment earlier in the course of his presentation, when considered against the ongoing nature of his "nonspecific memory impairments," were "very suggestive" of a psychosomatic illness—and felt the similar positive response to Ativan was consistent. *Id.* at 53. On discharge, D.M.'s differential diagnosis included conversion disorder, functional quadriplegia, functional aphasia, and resolved constipation and dehydration. *Id.* at 66. But his symptoms and responses as observed during the hospitalization itself were "much more consistent with a psychosomatic conversion disorder rather than true catatonia." *Id.* at 67.

Thereafter, however, other treaters continued to propose conversion disorder as a reasonable diagnosis. On March 15, 2019, for example, D.M. reported to MHCH's emergency department again. Ex. 7 at 49–53. Supervising physician Moira Black, M.D., prepared an addendum to D.M.'s medical record from that day. *Id*. at 52–53. In it, Dr. Black offered the view that D.M. had conversion disorder,

but that his parents "refused to understand and believe the diagnosis." *Id*. at 53. Dr. Black added that Petitioners believed that D.M. had "some kind of inflammation of the brain," even though his medical history revealed that past MRIs were normal, and an extensive rheumatological work-up was negative. *Id.* An April 2019 pediatric evaluation with a new treater also resulted in an impression of conversion disorder, emphasizing again the degree to which prior work-ups for the existence of some infectious/autoimmune disease had produced negative results. Ex. 13 at 60–69. It was also noted at this time that a positive response to Ativan was "not consistent with autoimmune disease." *Id*. at 68; *see also* Ex. 8 at 20 (late April neurology appointment, at which time treater noted no "obvious information" that D.M. had an autoimmune-type encephalopathy, despite his reported "rather dramatic response to intravenous steroids" during a previous hospitalization).

Subsequent repeated testing for autoimmune encephalitis or some associated autoimmune disease have produced negative results. *See, e.g.*, Ex. 4 at 64 (panel performed by Mayo Clinic), 53–58 (July 2019 lab testing, including endocrine studies and an autoimmune neurology antibody comprehensive panel, which produced negative results). Accordingly, at a follow-up neurology appointment, the relevant treater noted that D.M. had been tentatively diagnosed in the past with a possible autoimmune disorder, but that tests for autoimmune encephalitis "were not revealing of that diagnosis." Ex. 8 at 5–6. No other records past this point in time (beyond what is discussed below) have been filed.

II. Expert Reports and Treater Evidence Offered by Petitioners

A. *Expert Report – Justin Willer, M.D.*

Dr. Willer, a neurologist, prepared two written reports in this case. *See* Report, dated November 30, 2022, filed as Ex. 15 (ECF No. 20-1) ("First Willer Rep."); Report, dated May 10, 2023, filed as Ex. 19 (ECF No. 26-1) ("Second Willer Rep."). Dr. Willer opines that D.M. experienced an autoimmune encephalitis attributable to the flu vaccine administered to him in November 2018.

Dr. Willer received his undergraduate degree from Columbia College of Columbia University and his medical degree from the University of Health Sciences/The Chicago Medical School. *See* Curriculum Vitae, filed as Ex. 16 (ECF No. 20-2) ("Willer CV") at 1. Beginning in 1995, he has held hospital appointments at University Hospital, Long Island College Hospital, Maimonides Hospital Medical Center, and Kings County Medical Center, but he has not treated pediatric patients since 2000. Willer CV at 1. He has also held academic appointments as a Neuromuscular Consultant and Assistant Professor of Clinical Neurology at the State University of New York, HSC at Brooklyn. *Id*. He is licensed to practice medicine in New York, New Jersey, and Florida, and is board certified by the American Board of Psychiatry and Neurology, with added qualifications in clinical neurophysiology, and American Board of Electrodiagnostic Medicine. *Id.* at 2.

First Report

Dr. Willer began his first report with a summary of materials he had reviewed, plus a recap of D.M.'s medical history (which he repeated later in the same report). First Willer Rep. at 2–10, 17–22. He then provided an overview of autoimmune encephalitis, deeming it "an immune-related disease affecting the central nervous system with a broad range of presentations." *Id.* at 11. He also noted that while it includes "closely related disease processes," with common neuroimaging findings and clinical features, the precise version of encephalitis depends on the relevant, disease-driving autoantibodies, providing three overall subclasses (Group I, Group II, and "systemic autoimmunity with encephalopathy"). *Id.* Dr. Willer noted generally the kinds of treatments deemed effective for it. *Id.* at 13–14.

EEG[6] scanning can aid in diagnosis when the form of encephalopathy presents with seizures. First Willer Rep. at 12. By contrast, early MRI testing did not always confirm its presence. *Id.* at 12–13. Testing of the cerebrospinal fluid also was not often confirmatory. *Id.* at 13. A number of different immune-mediated mechanisms likely propagate autoimmune encephalitis, including molecular mimicry, B cell activation, or inhibition of existing immunoregulatory cells. *Id.;* A. Schattner, *Consequence or Coincidence? The Occurrence, Pathogenesis and Significance of Autoimmune Manifestations after Viral Vaccines*, 23 Vaccine 3876 (2005), filed as Ex. 17(d) (ECF No. 20-6) ("Schattner"). At the same time, however, half of all autoimmune encephalitis cases yield negative antibody-testing results. First Willer Rep. at 13.

Autoimmune encephalitis can be caused by cancer (and hence, Dr. Willer noted, cancer screenings are called for when encephalitic symptoms are clinically evident). First Willer Rep. at 12. But he also maintained that it could be vaccine-induced. For initial support, Dr. Willer referenced a number of studies or case reports associating the Hepatitis B vaccine (which is not at issue in this case) and autoimmune encephalitis, with onset occurring within days to three months of vaccination. *Id.* at 12. Dr. Willer provided no explanation as to why such studies involving a distinguishable vaccine had bearing on this case, however.

Turning to the claim at issue, Dr. Willer maintained the flu vaccine had likely caused D.M.'s injury. Autoimmune encephalitis best explained that injury, given D.M.'s responsiveness to steroids. First Willer Rep. at 25. His injury also likely had a monophasic course, even if that was uncommon for individuals suffering from some form of encephalitis. *Id.*; A. Tourbah et al., *Encephalitis after Hepatitis B Vaccination - Recurrent Disseminated Encephalitis or MS?*, 53 Neurology 1, 5 (1999), filed as Ex. 17(e) (ECF No. 20-7) ("Tourbah") (reporting a monophasic presentation in one of the study's eight patients). Many negative findings from D.M.'s history that seemed facially inconsistent with autoimmune

[6] "Electroencephalogram" is defined as "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. The normal dominant frequency of these potentials is about 8 to 10 cycles per second and the amplitude about 10 to 100 microvolts. Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." *Electroencephalogram*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15813 (last visited Jan. 5, 2024).

encephalitis were waived aside by Dr. Willer. For example, an "absence of white matter abnormalities" on MRI was not found in even half of encephalitis patients, meaning the lack of such evidence in this case did not matter. First Willer Rep. at 25; S.K. Lee et al., *The Laboratory Diagnosis of Autoimmune Encephalitis*, 6 J. Epilepsy Rsch. 45, 49 (2016), filed as Ex. 17(g) (ECF No. 20-9) ("Lee"); L. Solnes et al., *Diagnostic Value of ^{18}F-FDG PET/CT Versus MRI in the Setting of Antibody-Specific Autoimmune Encephalitis*, 58 J. Nuclear Med. 1307, 1311 (2017), filed as Ex. 17(h) (ECF No. 20-10) ("Solnes") (finding that 56.5% of the studied patients had no abnormal finding on MRI). The same was true for no positive findings for putatively-causal auto-antibodies. Lee at 49.

Dr. Willer found support for his proposed diagnosis of autoimmune encephalitis from the record evidence of D.M.'s medication response—noting several medical records suggesting a significant improvement in D.M.'s symptoms following receipt of steroidal treatments. First Willer Rep. at 25; Ex. 15 at 23; Ex. 11 at 1146 (documenting that approximately three hours after first steroid, D.M.'s speech returned to normal, and his memory had gradually improved). However, as discussed above, several contemporaneous treaters were *reluctant* to attribute D.M.'s initial improvement to the intravenous steroids, as "the cellular effect of steroids do not happen immediately with administration of the medication." Ex. 11 at 32. Dr. Willer deemed such contemporaneous treater statements to be lacking in probative value, since the amount of time that elapsed between administration of the intravenous steroids and the initial improvement had not been documented. First Willer Rep. at 7. (In fact, this is not true).

Regarding timeframe for onset, Dr. Willer pointed to the three-day span from vaccination to D.M.'s difficulty waking up on the morning of October 11, 2018, deeming it "shorter than the median interval" but "within the realm of possibility." First Willer Rep. at 22. It was also consistent with study findings he had referenced elsewhere in the report. One item of literature he offered noted a median time from vaccination to onset of four days, within a range of immediate onset to 730 days. First Willer Rep. at 14; S. Martin et al., *Anti-NMDA Receptor Encephalitis and Vaccination: A Disproportionality Analysis*, 13 Frontiers Pharmacology 1, 3 (2022), filed as Ex. 17(i) (ECF No. 21-1). Other case reports observed onsets within a few days to almost three months. D. Endres et al., *Psychiatric Presentation of Anti-NMDA Receptor Encephalitis*, 10 Frontiers Neurology 1, 2 (2019), filed as Ex. 17(j) (ECF No. 21-2) (reporting a time from vaccination to onset of symptoms of less than three days post-vaccination); Tourbah at 2.[7]

In offering this aspect of his opinion, however, Dr. Willer leaped right over the fact of D.M.'s football injury that most-immediately preceded his display of concerning behaviors. He referenced some record discussing the injury, in connection with the symptoms D.M. later experienced. First Willer Rep. at 22–23. But he went right into opining about the timeframe association. *See, e.g.*, *Id.* at 23.

At best, Dr. Willer (incredibly, given the medical record) *denied* D.M. was harmed during the football game at all. He maintained instead that D.M. had not likely had a concussion, because (a) no

[7] Dr. Willer has also referenced some case reports of encephalitis-like conditions reported after receipt of the COVID-19 vaccine, but the formulation for that vaccine, as well as the wholly-distinguishable mechanism by which it functions, is so completely different from the inactivated flu vaccine at issue in this case that these items of literature do not merit discussion.

behavior changes were noted until after the game's completion, (b) D.M. never lost consciousness, and (c) no adults present at the game observed any strange behavior. First Willer Rep. at 24. In addition, Dr. Willer noted that the neuropsychologic assessment that D.M. underwent in early November 2018 did not produce results thought to reflect the presence of a traumatic brain injury (although that same finding is consistent with Respondent's contention that D.M.'s overall presentation was partially attributable to a conversion disorder rather than significant neurologic injury). *Id.*

Dr. Willer (at the time of preparation of this first report) did allow for the possibility of a conversion disorder as explanatory, pending a neuropsychological evaluation not then performed. First Willer Rep. at 24. He even noted evidence in the record supportive of this. *Id.* at 24–25. But he expressed doubt about its validity, noting that treaters who had embraced the diagnosis had failed to take into account the lack of risk factors specific to D.M. (whose pre-vaccination history did not reveal reasons for concern about mental health or the kinds of stressors that might cause a conversion disorder). *Id.* at 25. He also maintained that, to the extent D.M. had suffered a conversion disorder, the purported autoimmune encephalitis likely had *caused it* in the first place. *Id.* Dr. Willer explained that the severity of conversion disorder symptoms typically correlates with more frequent early and later adverse life events—none of which appear to exist in the present matter. *Id.* at 15; V. Voon et al., *Emotional Stimuli and Motor Conversion Disorder*, 133 Brain 1526 (2010), filed as Ex. 17(n) (ECF No. 21-6); D.L. Perez & C.W. LaFrance, *Nonepileptic Seizures: An Updated Review*, 21 CNS Spectr. 239 (2016), filed as Ex. 17(o) (ECF No. 21-7).

Second Report

Dr. Willer's second report relied in part on the contents of the neuropsychologic evaluation Petitioners obtained for D.M. in May 2023, and he reiterates its findings. Second Willer Rep. at 1–3. Dr. Willer noted that D.M. had refused to cooperate on a prior assessment, conducted within a month of vaccination, but that it appeared from the record that this "represented a poor effort on the part of [D.M.] and not malingering," so he deemed the more recent evaluation consistent with that finding. *Id.* at 3. The kinds of deficits D.M. displayed were in fact consistent with the findings of some case reports involving patients with NMDAR encephalitis. *Id.* at 4; A.R. Loughan et al., *Anti-N-Methyl-D-Aspartate Receptor Encephalitis: A Review and Neuropsychological Case Study*, 30 Clin Neuropsychol. 150 (2016); E. Cainelli et al., *Neuropsychological and Psychopathological Profile of Anti-NMDAR Encephalitis: A Possible Pathophysiological Model for Pediatric Neuropsychiatric Disorders*, 34 Neuropsychol. 1309 (2019).[8] Of course, D.M. has never been so diagnosed—and certainly never displayed the other symptoms associated with this Anti-NMDAR encephalitis—a very severe autoimmune disease typically leading to hospitalization, and often featuring severe developmental regression as well.[9] Nevertheless, Dr. Willer contended that the 2023 neuropsychologic findings were consistent with "the presence of an

[8] In reviewing the docket, I note that Petitioner referenced, but did not file several items of literature cited in Dr. Willer's second report.

[9] *See Lehner v. Sec'y of Health & Hum. Servs.*, No. 08-554V, 2015 WL 5443461, at *17-18 (Fed. Cl. Spec. Mstr. July 22, 2015)

organic mental syndrome," while excluding the possibility of a "primary psychiatric etiology." Second Willer Rep. at 4.

Otherwise, Dr. Willer repeated his prior opinion—that D.M. had experienced an autoimmune-mediated encephalitis. Second Willer Rep. at 4. In support, he emphasized again D.M.'s purported response to steroids as corroborating the nature of his illness, along with his assertion that any conversion disorder displayed by D.M. was the secondary consequence of his encephalitis, rather than an overarching explanation for his symptoms. *Id.* He also reiterated the contention that a concussion suffered during a football game could not explain D.M.'s behavior, since he had not displayed noticeable symptoms at the game, and that his "executive function" had not been impacted, as would be expected with a concussion. *Id.* Dr. Willer concluded that the timeframe for onset was medically acceptable, noting again that since literature like Martin allowed for the possibility of vaccine-induced onset from one day to up to almost *two years* post-vaccination, two days was reasonable as well. *Id.* at 5.

B. *Neuropsychological Evaluation*

To support their contention that D.M.'s condition is not best understood (at least primarily) as conversion disorder, Petitioners had D.M. evaluated in May 2023 by Kit W. Harrison, Ph.D. *See* Neuropsychological Evaluation, dated May 4, 2023, filed as Ex. 18 (ECF No. 25-1) ("Harrison Evaluation").

The Harrison Evaluation itself does not include a CV or resume establishing Dr. Harrison's qualifications, and such a document was never filed. However, the letterhead for the Harrison Evaluation sets forth Dr. Harrison's professional business entity ("Kit W. Harrison Ph.D. & Associates"), and that entity has a website that includes some details regarding Dr. Harrison's background. Kit W. Harrison, Ph.D. & Associates, http://www.kitharrisonphd.com/home.html (last visited Jan. 5, 2024). It states that Dr. Harrison is a psychologist licensed in the State of Texas since April 1983, and that he performs forensic psychological evaluations (mostly "within the parent-child relationship which can be ordered by family district and county courts as well as hired as an expert witness by counsel in said cases"). He was previously a faculty member in the Department of Neurology at Baylor College of Medicine, and was a co-director and founder of the first clinic in Texas devoted to the problems of concussions and mild traumatic brain injury. He also performs training and workshops for doctors, lawyers, and members of the judiciary including speaking annually at the Conference for the Center for the Judiciary. Dr. Harrison's evaluation expressly sets forth, in a disclaimer, that "[t]he evaluation reflects the patient's status at the time of the assessment and may not be applicable to her past or future functioning in all instances."

The Harrison Evaluation indicates that D.M. was seen in May 2023—not only in the course of the litigation of the claim, but over four years after the purported vaccine event. At that time, a personal medical history was taken, which included the Petitioners' allegations of a "severe adverse reaction" to the vaccination at issue (despite an absence of record support for that contention, as noted above). Harrison Evaluation at 1. The history also states that autoimmune testing performed in 2017 or 2018 "possibly indicated features of Guillain-Barre," plus some suggestion of conversion disorder. *Id.* And the

history noted family problems as well that seemed to have been thought to possibly be impacting D.M.'s well-being. *Id.*

Dr. Harrison reports having performed a number of tests to assess D.M.'s neuropsychological status. Harrison Evaluation at 2, 4–8. He provides specific results from the testing therein. Based on the results, Dr. Harrison deemed D.M. to be average in cognitive and intellectual function, with "no suggestion of impairment of psychopathology." *Id.* He also saw no evidence of developmental delay or unusual behaviors or motor function. *Id.* at 3. Nevertheless, Dr. Harrison also noted the existence of some "Adjustment Disorder with Mixed Anxiety and Depressed Mood" symptoms from the "period of disability" (meaning prior to the evaluation), adding that this likely had set D.M. back, causing "lost developmental successes." *Id.* at 3.

The Harrison Evaluation ultimately settled on a proposed diagnosis for D.M. of "unspecified neurocognitive disorder; adjustment disorder with mixed anxiety and depressed mood." Harrison Evaluation at 7. Dr. Harrison emphasized learning deficiencies (and in particular speed in processing), and proposed more outpatient neurocognitive rehabilitation to remedy such deficits. *Id.* at 8. He also recommended counseling for the "persisting emotional features" of the illness. *Id.* The Harrison Evaluation does not, however, address the issue of vaccine causation, does not mention the football injury D.M. experienced or its potential relationship to his subsequent symptoms, and also does not opine at all on whether D.M. had experienced a conversion disorder—whether due to vaccination or some other cause.

III. Procedural History

The claim was initiated a little more than two years ago, in October 2021. After going through "pre-assignment review" (a process used by the Office of Special Masters to ensure that the most important documents and records relating to the claim have been filed), the Petition was activated and assigned to my docket. Respondent filed his Rule 4(c) Report in March 2022, and then I ordered Petitioners to obtain an expert report in support of the claim, which occurred in the fall of 2022 (with the Harrison Evaluation filed in the spring of 2023). In lieu of offering an expert report in reaction, Respondent moved for dismissal of the claim in July 2023. The matter is now fully briefed and ripe for resolution.

IV. Parties' Arguments

A. *Respondent*

Respondent contends that Petitioners cannot meet the foundational requirement of establishing a cognizable vaccine injury. While Respondent admits that there is *some* record support for an encephalitis diagnosis (although it stems from evaluations or tests performed more than six months from the date of vaccination), he maintains that the weight of evidence is unsupportive of that proposed injury. Br. at 14. Rather, numerous treaters who saw and evaluated D.M. did not conclude that any form of autoimmune encephalitis was present—and they did so on the basis of in-person exams and observations plus testing

and other clinical evaluations. *Id.* at 14. Such evidence persuasively favors conversion disorder over Petitioner's favored injury. *Id.*

Petitioners' experts, however, have not (in Respondent's estimation) rebutted in any persuasive form those treater findings. Dr. Willer's opinion, Respondent argues, is "confounding at best." Br. at 17. Dr. Willer's embrace of autoimmune encephalitis is based in part on D.M.'s alleged responsiveness to steroids—even though "multiple treating physicians" rejected any such association. *Id.* at 17–18. The time it took to show this improvement was simply too fast. *Id.* at 18. Dr. Willer's view that any conversion disorder D.M. displayed was likely attributable to his underlying autoimmune injury did not rely on the Harrison Evaluation (since it did not embrace the conversion disorder interpretation of D.M.'s conduct), and otherwise was poorly-substantiated as well as rejected by numerous treaters—who did not accept an encephalitis diagnosis, and otherwise did not embrace conversion disorder to be explained by some vaccine-caused injury. *Id.* at 18–19.

Other than disputing the favored diagnosis, Respondent argued in his brief that Petitioners had not met the three prongs applicable to a causation-in-fact claim as established by the Federal Circuit in in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (2005). Br. at 19. The "can cause" prong had not been preponderantly established—or even spelled out in detail, with Dr. Willer mostly seeming to base his opinion on the temporal association between vaccine and onset, or studies involving the hepatitis B vaccine. *Id.* at 20. Petitioners also did not establish the flu vaccine was to blame for D.M.'s presentation. And their timeframe arguments for *Althen* prong three were also inadequately supported. *Id.* at 21. Dr. Willer had relied for this part of his opinion on literature involving a specific kind of autoimmune encephalitis (anti-NMDA receptor encephalitis) that involved onsets longer than the two to three days at issue here, but it has not been shown that this is the kind of encephalitis D.M. had, and his course was otherwise inconsistent with the Endres case report referenced for this argument. *Id.* at 22. Nothing had been offered to show a likely onset timeframe specific to the flu vaccine.

B. *Petitioners'*

Petitioners admittedly note a dispute in the medical records regarding D.M.'s diagnosis—some treating physicians opined that D.M. suffered from a concussion, while others discussed autoimmune encephalitis as a possibility. Opp. at 19. Despite some of the discrepancies in diagnosis, Petitioners maintain that Dr. Willer has provided sufficient testimony to support a diagnosis of autoimmune encephalitis, subsequently leading to the development of conversion disorder. *Id.* Dr. Willer opined that autoimmune encephalitis was the trigger for D.M.'s conversion disorder—further explaining why risk factors, such as physical or sexual abuse, were absent. *Id.* at 19–20. Moreover, Dr. Willer argued that D.M.'s symptoms are inconsistent with a concussion, given that many symptoms associated with concussion are immediate and not as delayed as in the present case. *Id.* at 20. Dr. Willer further opined that with many traumatic brain injuries the executive function of an individual is affected, but not in D.M.'s case. Thus, D.M.'s presentation was more likely a result of autoimmune encephalitis according to Dr. Willer. *Id.*

Petitioners further contend that ample medical literature establishes a medical mechanism by which vaccination can and does trigger autoimmune encephalitis. Opp. at 20; *see also* Schattner, Tourbah, Lee, and Solnes. Moreover, Dr. Willer opined that the onset of D.M.'s symptoms occurred no sooner than two days post-vaccination—a plausible timeframe for onset of an autoimmune disease to present following receipt of vaccination. Opp. at 21. Accordingly, Petitioners argue that there is sufficient evidence to support their burden of proof. *Id.* at 25.

V. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[10] Petitioners allege a causation-in-fact claim (and could not otherwise allege a Table claim of encephalopathy or encephalitis after receipt of the flu vaccine: there is no such claim).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical

[10] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at

1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied,* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's

discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to

contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of

the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioners' claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal.

Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

Here, as in many Program cases, determination of the relevant injury is critical to the claim's success. *Broekelschen*, 618 F.3d at 1346. Petitioners seek to characterize D.M.'s post-vaccination condition as some form or autoimmune-caused encephalitis (which, if established, would provide the entry to determining that it could be vaccine-associated). No other version of injury is alleged, and thus the first matter for determination (and potentially the sole matter) is to evaluate if the evidence preponderantly supports an autoimmune encephalitis as the best explanation for D.M.'s condition.[11]

Here, there is clinical evidence of D.M.'s post-football game behavioral changes, and that they were alarming enough to Petitioners and treaters to result in his hospitalization in November 2018. But evidence of an *autoimmune* injury that might be vaccine-related is scant. No testing at all is confirmatory of the existence of this kind of injury, and no treaters ever settled on such a diagnosis. There is also no evidence of any close-in-time (meaning the first hours to days post-vaccination) reaction to the vaccine, with D.M.'s symptoms only manifesting *after* his football injury, which treaters at the time deemed a concussion.

Petitioners' expert input does not at all aid their argument that D.M. experienced a vaccine-related injury. The essence of Dr. Willer's opinion seems to be that because D.M.'s symptoms

[11] Although this is a non-Table case, the Table definition of "encephalopathy" provides some insights into the factors deemed sufficient by Respondent to establish a claim in which causation is presumed—and thus what would be particularly strong evidence of a vaccine injury in this context. See 42 C.F.R. § 100.3(a)(II)(B)(2018). Petitioner herein is not obligated to meet these requirements, but some brief review of them helps illuminate the kinds of symptoms that would be associated with an encephalopathy resulting in developmental deficits.

Table claimants seeking to prove a vaccine-caused encephalopathy must establish both that the injured party experienced an "acute" encephalopathy—typically evidenced by a decreased change in consciousness (as that term is defined in the Qualifications and Aids to Interpretation, 42 C.F.R. § 100.3(c)(2)(2018)) of sufficient severity to warrant hospitalization—and that the encephalopathy subsequently became "chronic" (that is, it lasted for at least six months). *Thompson v. Sec'y of Health & Hum. Servs*., No. 15-1498V, 2017 WL 2926614, at *7–8 (Fed. Cl. Spec. Mstr. May 16, 2017). The acute encephalopathy must manifest within three days/seventy-two hours, and if alleged to have been experienced by a child less than eighteen months old, must be "indicated by a significantly decreased level of consciousness that lasts at least 24 hours." 42 C.F.R. § 100.3 (2017).

A causation-in-fact claim alleging encephalopathy, by contrast, is not subject to the Table's stringent defined requirements. But where encephalopathy as the injury is alleged, it must be supported by preponderant proof, and that evidence must establish more than simply a subsequent neurologically-derived symptom (since virtually any injury impacting the brain could credibly be deemed some form of encephalopathy)..

manifested post-vaccination, and because in other contexts vaccines are associated with autoimmune injury, it can be reasonably concluded this happened to D.M. But this opinion is not sufficiently rooted in record proof to find it persuasive. Rather, it seems to epitomize the kind of "post hoc ergo propter hoc" reasoning that numerous decisions have rejected. *See Galindo v. Sec'y of Health & Hum. Servs.*, No. 16-203V, 2019 WL 2419552 (Fed. Cl. Spec. Mstr. May 14, 2019) (citing *U.S. Steel Group v. United States*, 96 F. 3d 1352, 1358 (Fed. Cir. 1996) ("[b]ut to claim that the temporal link between these events proves that they are casually related is simply to repeat the ancient fallacy: *post hoc ergo propter hoc*").

Dr. Willer also proposes that the record reveals D.M. responded to steroid treatments, thus indirectly supporting the conclusion that the injury he was experiencing was autoimmune in nature. But numerous treaters expressly rejected that conclusion, and placed no significance in the seeming benefit of the administration of such medication. Ex. 1 at 121; Ex. 11 at 33, 53, 933–36. I deem their contemporary views to be deserving of greater weight than Dr. Willer's after-the-fact opinion. Moreover, there is record evidence that later on, when D.M. received Ativan, a sedative, he *also* immediately experienced improvement—something contemporaneous treaters viewed as supportive of a conversion disorder diagnosis, but not otherwise proof of any other particular underlying explanation for his clinical symptoms. *See, e.g.*, Ex. 1 at 68 ("[t]emporal improvement with Ativan more likely coincidental"). And Ativan is not a treatment associated with an autoimmune injury in any event.[12]

The Harrison Evaluation is of even less help. It takes no position at all on the primary disputed questions. Arguably, it could be construed to *undermine* a conversion disorder diagnosis, in favor of a milder depressive reaction to D.M.'s personal circumstances at home. But even if D.M.'s post-vaccination difficulties are not wholly reflective of a conversion disorder, this does not mean the vaccine was more likely to blame simply because it predates onset. And the Harrison Evaluation was performed too long after the vaccination to read it as persuasively ruling out a conversion disorder that would have occurred *four years before*—let alone behavior changes initially attributable to a physical injury.

And this raises a final, significant fact: the undisputed evidence of D.M.'s football injury. The record proof that this occurred—and that it was what first prompted Petitioners to seek treatment for D.M.—shines forth above all else in this case, and stands as a completely credible explanation for what sadly befell D.M. thereafter (at least close-in-time to it). Indeed, the first post-vaccination treatment of any kind that D.M. received came in response to the injury—and at that time, D.M. was reported to display the kinds of symptoms he is now alleged to have experienced due to vaccination, but just after the game. Ex. 1 at 37–40.

[12] In fact, some treaters considered D.M.'s seemingly-fast response to *both* steroids and Ativan to support the conclusion that he was suffering from a conversion disorder, given their disparate natures. *See, e.g.*, Ex. 11 at 54 (March 2019 pediatric psychiatry consultation, stating that "[p]resentation is similar to his last admission, which responded well to Ativan and steroids. However, his immediate response to treatment with continued nonspecific memory impairments were very suggestive of a psychosomatic illness. Given the way that the pt responded to the Ativan over the weekend, this is again c/w Conversion d/o, and despite the fact that he is insistent that he does not have psychiatric issues, the pt would likely benefit from the PATH program. We do not recommend sending the pt home with Ativan").

Dr. Willer's efforts to explain away the football injury are wholly unconvincing. The fact, for example, that D.M.'s injury was not *immediately* understood to be a concussion by bystanders present at the football game does not mean it is not a reasonable explanation for what occurred. Initial treaters largely concluded that this is what had transpired in D.M.'s case. Ex. 1 at 8–9. And while later brain scans did not reveal either any underlying abnormality or harm, this fact does not remove the possibility of some form of transient concussive harm as the most likely proximate explanation for D.M.'s immediate, post-football game behaviors. (Indeed, as Dr. Butler opined in December 2018, "relatively minor head trauma" could produce brain injury even in the absence of strong evidence from imaging. *See* Ex. 1 at 121). Later on, continuation of those same behaviors may have been the product of the conversion disorder D.M. was thought to be experiencing—a secondary explanation for his symptoms more consistent with the record than Dr. Willer's contention that conversion disorder was the product of an autoimmune illness.

The medical record thus better supports two independent, temporally-overlapping explanations for D.M.'s post-vaccination symptoms—effects of a concussion immediately after the October 2018 football game, or conversion disorder manifesting later on. Such evidence greatly outweighs the far more limited evidence suggesting the presence of an autoimmune process as explanatory. This is of course not to say that the evidence *establishes* an explanation for D.M.'s condition (and I am not qualified to diagnose him in performing my duties as special master in any event). But the balance of proof does not preponderantly support the conclusion that any form of autoimmune injury occurred in this case attributable to the flu vaccine. That determination prevents Petitioners from succeeding in proving the alleged injury (as well as the second *Althen* prong—they cannot on this record prove the flu vaccine likely "did cause" D.M.'s symptoms, which are not likely reflective of an autoimmune encephalitis).

It is well-accepted in the Program that not all injuries are attributable to a prior vaccination, no matter how close-in-time the relationship. *Capizzano*, 440 F.3d at 1327. This is so even when there is *no* other competing explanatory evidence. Here, there is *ample* such evidence, and it cannot be evaded by providing the opinion of a practicing neurologist (Dr. Willer) willing to gainsay the clear and uncontroverted record. In the end, and as noted above, this is a case attempting to prove solely that symptoms that *followed* a vaccine were *caused* by it, mostly due to the temporal association, while disregarding, or unpersuasively dismissing, fairly obvious other record evidence deserving of substantial weight that goes to the nature of the injury. The matter is properly dismissed.

CONCLUSION

While I have sympathy for the Petitioners' efforts to ascertain the nature of D.M.'s condition and provide him treatment for it, this case relies on a diagnosis that is wholly rebutted by the record alone. D.M.'s onset of behavior symptoms had no more than a mere temporal relationship with vaccination—and have more compellingly been linked to a sports accident or other personal issues in his life. Having reviewed the medical records, expert reports, medical literature, and the parties'

respective arguments, I do not find that Petitioners have met their preponderant burden of proof. Accordingly, they have not established entitlement to an award of damages, and I must **DISMISS** the claim.[13]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[13] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.